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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,705	11/07/2000	Kenji Sakamoto	IKU0104PUSA	2404

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/17/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,705

Applicant(s)

SAKAMOTO, KENJI

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 11) filed on January 24, 2002 has been entered.
2. New claim added is numbered in correct. Claims 5-17 are drawn to non-elected claims. New claim added is corrected as claim No. 18.

Response to Arguments

3. Applicant's response to the office action (Paper No.15) is fully considered and deemed persuasive in part.
4. With respect to the rejection made in the previous office action under 35 U.S.C. 112, first paragraph, applicants' amendment and arguments have been considered and the rejection is withdrawn herein.
5. With respect to the rejection made in the previous office action under 35 U.S.C. 112, second paragraph, applicants' amendment and arguments have been considered and the rejection is withdrawn herein.
6. The following is the rejection made under 35 U.S.C. 102 (b) in the previous office action:

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Song et al. (Proc. Natl. Acad. Sci. USA., 90: 9085-9089, 1993).

Song et al. teach a method for human gastrin/cholecystokinin type B (CCK_B) receptor gene variants having two sizes short and longer isoforms (see page 9087, paragraph 2). Song et al. disclose that the method involves examining CCK_B receptor gene mRNA variants by comparing sequence of longer and shorter isoform in which the shorter isoform lacks a pentapeptide sequence (missing region) that is present in the longer isoform (see page 9088, lines 1-14). Song

et al. also disclose the cDNA sequence analysis of gastrin/CCK_B receptor isoforms (see page 9088, Fig. 4). Further, Song et al. discloses that the missing region, the penta peptide sequences cassette in gastrin/ CCK_B receptor may be of potential functional importance. Thus the disclosure of Song et al. meets the limitations in the claim 1.

Response to Arguments:

With respect to the rejection made in the previous office action under 35 U.S.C. 102(b), applicants' arguments have been considered and found not persuasive because the prior art (Song et al.) do teach the said method comprising comparing cDNA receptor variant sizes and identifying larger and shorter receptor variants as claimed in the instant application. Song et al. does teach the potential biological activity in G protein-coupled receptor function. With regards to functional antagonism against the ligand, Song et al. does teach CCK_b receptor antagonists and their role in discriminating ability with CCK_b receptor types (see page 9085, column 2, paragraph 1). Further, as noted following the phrase "functional antagonism" is indefinite and may represent new matter.

Also, the arguments relates to the peptide are not relevant, since the instant claim 1 lacks any functional requirement for the peptide. Therefore, the rejection is maintained herein since no specific peptide limitation is found in the instant claim 1.

7. With respect to the rejection made in the previous office action under 35 U.S.C. 103(a), Applicant's arguments with respect to claims 1-4, have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

8a. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "... functional antagonism" which is indefinite. No definition of the term was found in the specification. It is unclear what "functional antagonism" is. That is, is it something which blocks ligand activity, blocks receptor activity, inhibits cell growth, or acts to enhance cell growth.

8b. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)".

Here, the new limitation of "functional antagonism" in the claim 1 appears to represent new matter. A careful review by examiner of the specification, this word "functional antagonism" was not present. Thus the phrase "functional antagonism" lacks descriptive support in the specification.

Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song et al. (Proc. Natl. Acad. Sci. USA., 90: 9085-9089, 1993). And in view of Olsson et al. (USPN. 6,333,031).

Song et al. teach a method for human gastrin/cholecystokinin type B (CCK_B) receptor gene variants having two sizes short and longer isoforms (see page 9087, paragraph 2). Song et al. disclose that the method involves examining CCK_B receptor gene mRNA variants by comparing sequence of longer and shorter isoform in which the shorter isoform lacks a

pentapeptide sequence (missing region) that is present in the longer isoform (see page 9088, lines 1-14). Song et al. also disclose the cDNA sequence analysis of gastrin/CCK_B receptor isoforms (see page 9088, Fig. 4). Further, Song et al. discloses that the missing region, the penta peptide sequences cassette in gastrin/ CCK_B receptor may be of potential functional importance (see 9089, column 1, paragraph 1 and page 9085, column 2, paragraph 1). However, Song et al. did not teach producing active peptides with deletions or missing regions.

Olsson et al. teach a method for determining and producing biologically active peptides wherein Olsson et al. disclose that the method comprises receptor variants shorter (deleted or missing region) as compared to wild-type sequences (see column 12, lines 57-67, and column 13, lines 1-48). Olsson et al. also teach that the derived peptides have at least 75% identical to the activation sequence (missing region) of the receptor (see column 13, lines 49-62); the missing region could be chemically synthesized (column 12, lines 44-47, column 29, lines 15-25). Thus, the disclosure of Olsson et al. meets the limitations in the instant claims.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of identifying human gastrin/CCK_B receptor variants as taught by Song et al. with bioactivity assay as taught by Olsson et al. because Song et al. states that "the two receptor isoforms may contribute to functional differences in gastrin-and CCK-mediated signal transduction". One such functional attribute, expressly motivated by Olsson et al. is the delineation of bioactivity of receptor variants "for identifying receptor-specific sites of importance for receptor-specific sites of importance for receptor internalization, and for enhancing sensitivity to hormones and other agonists". An ordinary practitioner would have been

motivated to combine the teachings of Song et al. with Olsson et al. to develop a method for identifying biologically active receptor peptides.

No claims are allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Spe
Suryaprabha Chunduru
April 8, 2002



JEFFREY FREDMAN
PRIMARY EXAMINER